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Subject: Some actual news
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Some actual news

About Moderna adverse event reports

Alex Berenson
Aug 6

Covid vaccine maker Moderna received 300,000 reports of side effects after vaccinations over a three-month period following the launch of its shot, according to an internal report from a company that helps Moderna manage the reports.

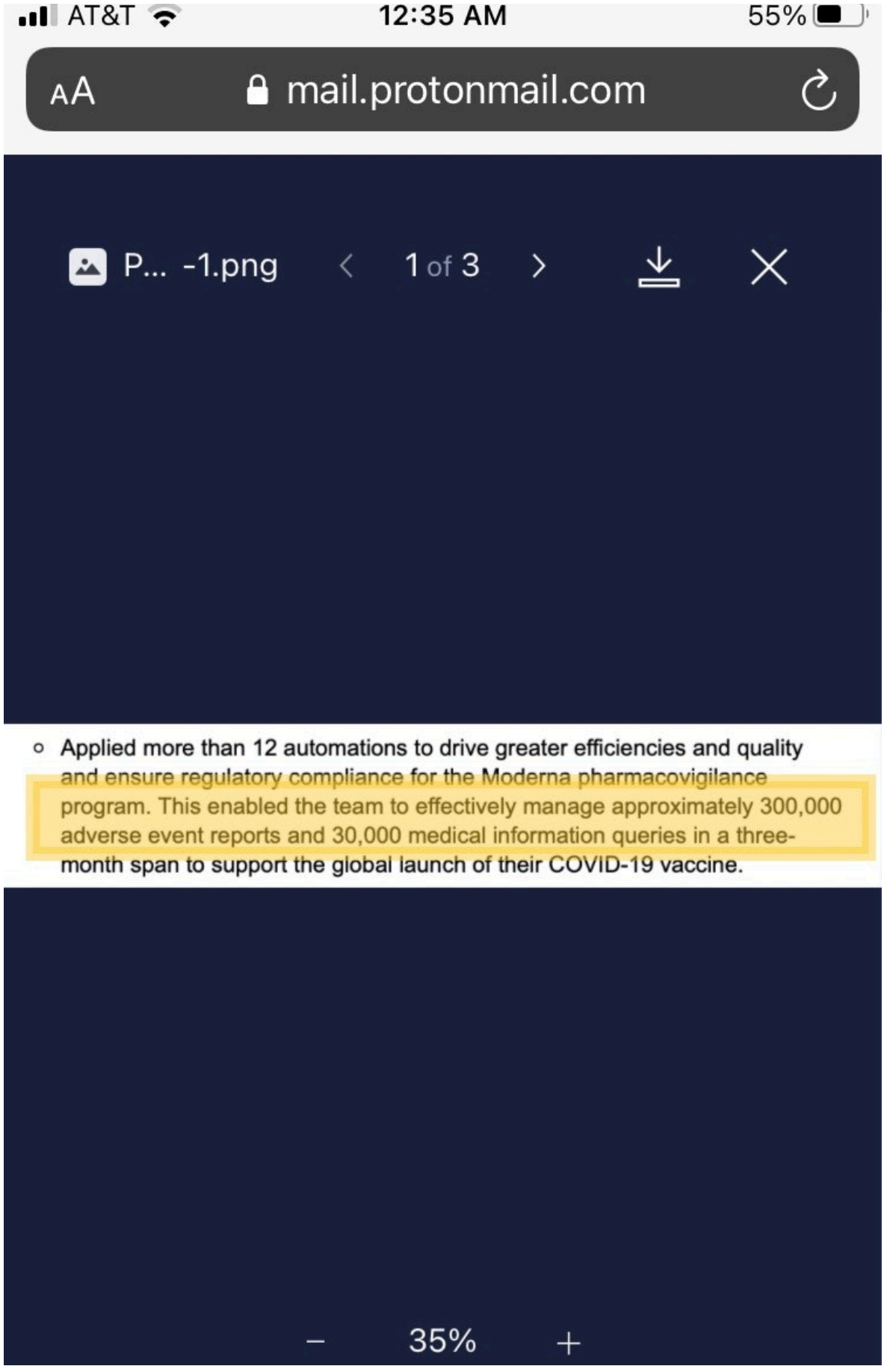
That figure is far higher than the number of side effect reports about Moderna's vaccine publicly available in the federal system that tracks such adverse events.

Vaccine manufacturers like Moderna are legally required to forward all side effect reports they receive to the Vaccine Adverse Events Reporting System, where they are made public each week.

Run by the Centers for Disease Control and Food & Drug Administration, the VAERS system is crucial to tracking potential problems with vaccines. It helped scientists determine the Covid vaccines may cause heart problems in young adults.

The reason for the gap is not clear. Moderna may simply still be processing the reports, though the number of reports about Moderna's vaccine in VAERS from the first half of 2021 remained almost flat this week.

Moderna and IQVIA, the company that works with Moderna to handle the reports, did not return emails for comment.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Applied more than 12 automations to drive greater efficiencies and quality and ensure regulatory compliance for the Moderna pharmacovigilance program. This enabled the team to effectively manage approximately 300,000 adverse event reports and 30,000 medical information queries in a three-month span to support the global launch of their COVID-19 vaccine.
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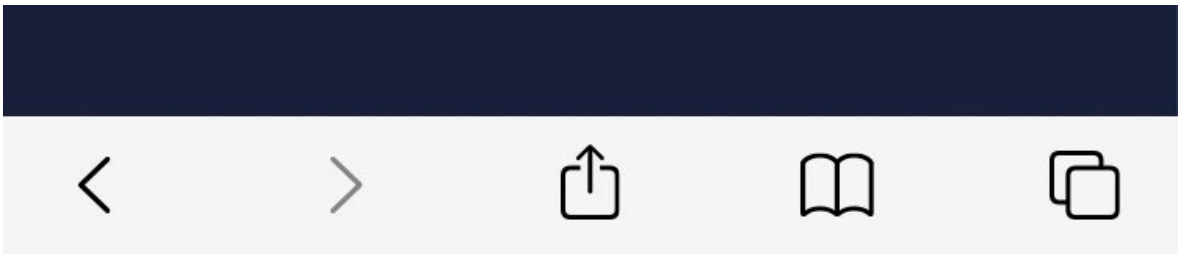

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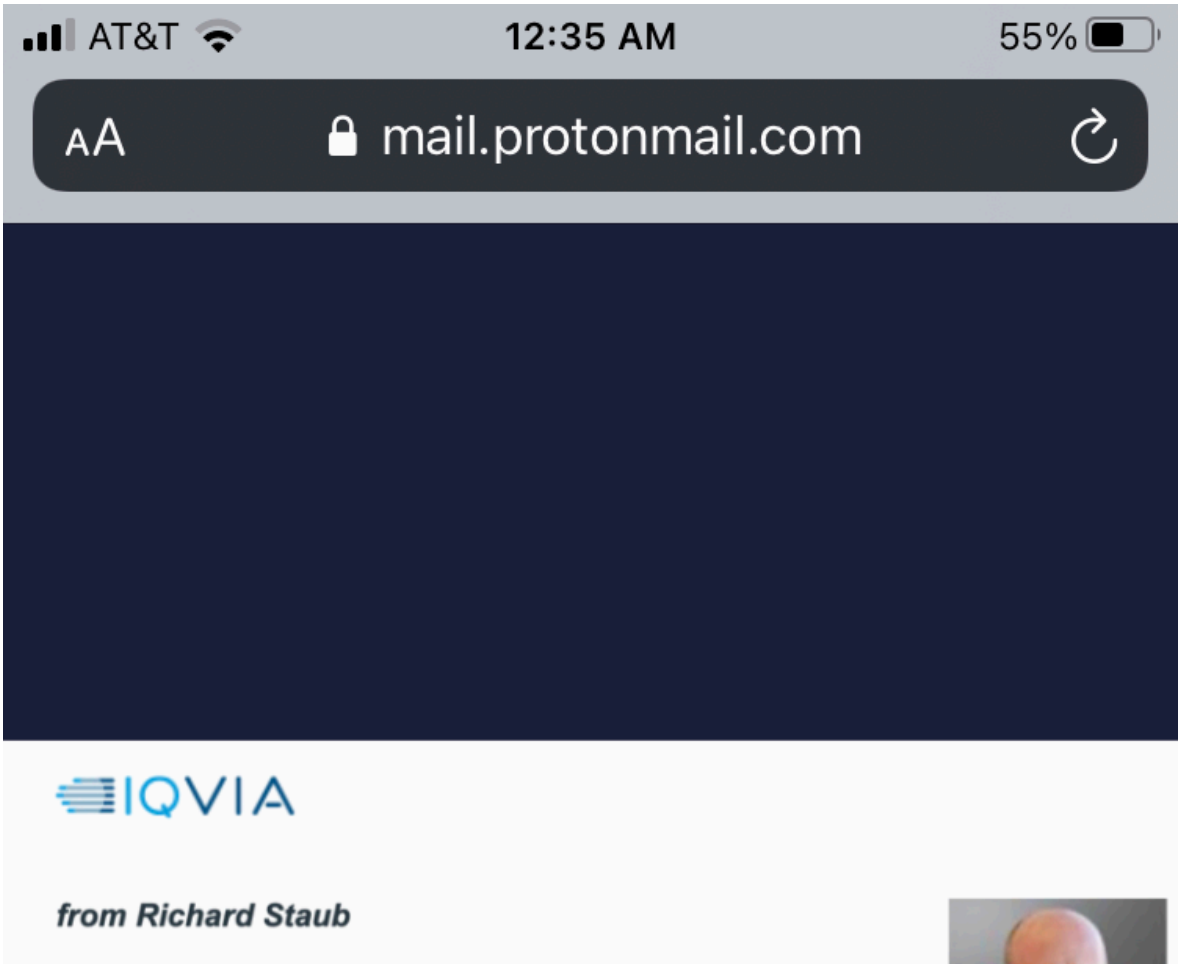
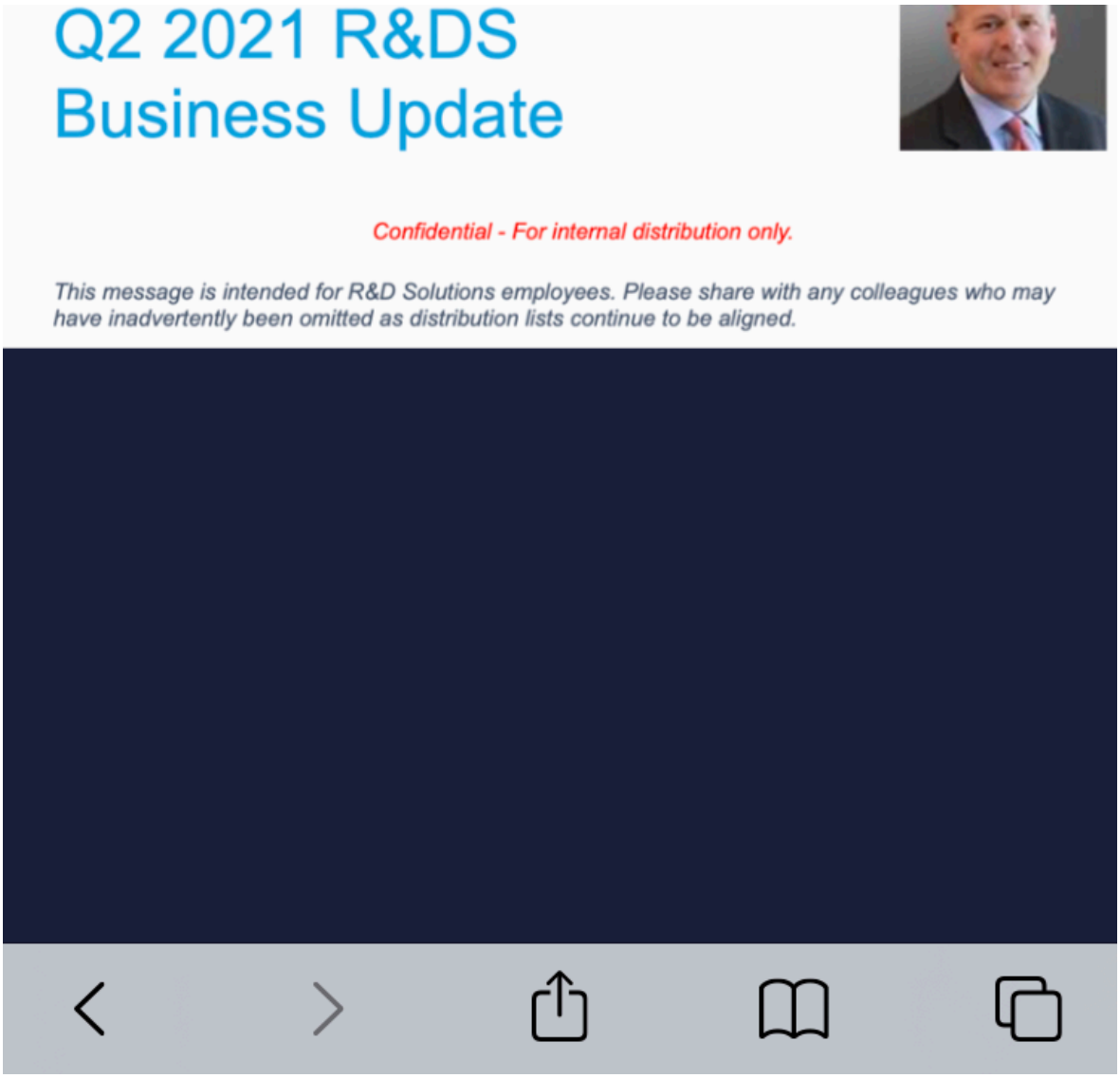
The 300,000 figure comes from an internal update provided to employees by IQVIA, a little-known but enormous company that helps drugmakers manage clinical trials. Headquartered in North Carolina, IQVIA has 74,000 employees worldwide and had $11 billion in sales last year.

Earlier this week, Richard Staub, the president of IQVIA's Research & Development Solutions division, sent a "Q2 2021 update" which was labeled "Confidential - For internal distribution only."





A person with access to the presentation provided screenshots of the relevant slide, which clearly explains the 300,000 side effect reports were received over “a three-month span” - not since the introduction of the vaccine in December - and differentiates between them and “medical information queries.”

The slide does not make clear what three months are covered but refers to the “global launch” of the vaccine, which essentially took place in the first quarter of 2021. Whether the slide is referring to January through March or April through June, the 300,000 figure dwarfs the number of reports in VAERS for the Moderna vaccine for either period.

A query of VAERS this morning reveals roughly 110,500 adverse events reports worldwide for Spikevax completed from January through March. All but 650 were in the United States. VAERS also includes 78,000 reports completed from April through June, including 71,400 in the United States.

Those figures overstate the number of reports Moderna has provided, because they include many reports from patients, physicians, and other health-care providers, as well as those from Moderna.

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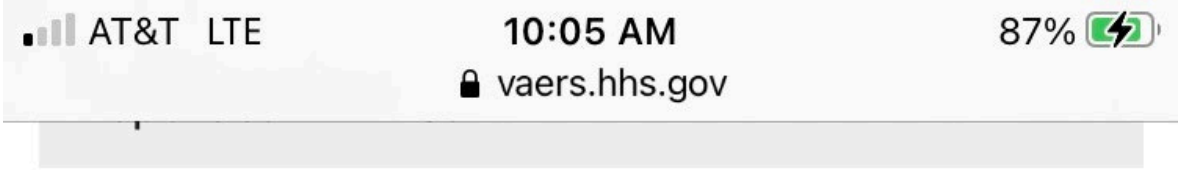
VAERS was established in 1990 and is jointly managed by the CDC and FDA, which contract with General Dynamics to administer it. It has struggled to keep up with the hundreds of thousands of reports it has received about the Covid vaccines since their rollout began in December. For much of the spring, it lagged months behind in making reports public.

VAERS is usually characterized as a voluntary system. But physicians and healthcare providers are required to report certain serious post-vaccine side effects, including deaths. However, the CDC and FDA have no real way to check if they are doing so.

Healthcare providers do have discretion over whether they report less serious side effects. Many have decided not to do so for the Covid vaccines, because the volume of reports is already so high.

However, vaccine manufacturers must forward ALL reports they receive, as the VAERS Website makes clear. It distinguishes between healthcare providers, who are "strongly encouraged" to report various events, and manufacturers like Moderna, who "**are required** [emphasis added] to report to VAERS all adverse events that come to their attention."



Healthcare providers are required by law to report to VAERS:

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccination
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

Healthcare providers are strongly encouraged to report:

- Any adverse event that occurs after the administration of a vaccine licensed in the United States, whether or not it is clear that a vaccine caused the adverse event
- Vaccine administration errors

Vaccine manufacturers are required to report to VAERS all adverse events that come to their attention.

Moderna's stock has nearly quadrupled this year as sales of the Covid vaccine have soared. On Thursday, the company reported $4.4 billion in sales and $2.8 billion in profits for the second quarter.

As of today's update, VAERS contains more than 3,000 reports of deaths following Moderna vaccinations.

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